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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,388	11/24/2000	Nobutaka Yamamoto	001554	3765

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/718,388

Applicant(s)

YAMAMOTO ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in the present application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 August 2002 has been entered.

Response to Amendment

The rejection of claims 1-15 under 35 U.S.C. 102(b) over Green et al. (US Patent No. 4016036) has been withdrawn in view of Applicant's Amendment and Arguments filed 2 August 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al. (U.S. Patent No. 4,940,666).

The invention of the instant claims is broadly drawn to a method comprising the inoculating, culturing and killing of fibroblast cells, specifically 3T3 cells, by freezing, drying or irradiating. Target cells are then inoculated and cultured with the target cells. The method of the present claims also calls for the removal of fibroblast cells from the culture.

Boyce et al. teach a method wherein fibroblast cells were grown in lethally irradiated 3T3 cells. Boyce et al. like the present claims call for the use of lethally irradiated 3T3 cells. Given that both Boyce et al. and the present invention grow epidermal cells on lethally irradiated 3T3 cells, the extracellular matrix recited in Applicant's claims would be inherent to the method of Boyce et al. See column 2, lines 43-47. When Applicant claims a property, which is inherently present in the prior art, the property does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Boyce et al. additionally teach that the 3T3 cells were removed from the culture, thus meeting the limitations of claims 2 and 3. See column 2, line 55.

Claims 1, 4, 5, 7-12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Rheinwald et al. (Nature Vol.265 1977).

The invention of the instant claims is broadly drawn to a method comprising the inoculating, culturing and killing of fibroblast cells, specifically 3T3 cells, by freezing, drying or irradiating. Target cells are then inoculated and cultured with the target cells.

Rheinwald et al. teach that keratinocytes depend on the support of fibroblasts to initiate growth and proliferation. The reference teaches that culture dishes having lethally irradiated 3T3 cells are inoculated with keratinocytes. See page 421-422.

Claim Rejections - 35 USC § 103

Claims 1-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. as applied to claims 1-5, 7-12, 14 and 15 above.

The invention of the instant claims is broadly drawn to a method comprising the inoculating, culturing and killing of fibroblast cells, specifically 3T3 cells, by freezing, drying or irradiating. Target cells are then inoculated and cultured with the target cells. The method of the present claims also calls for the removal of fibroblast cells from the culture. The method of the instant claims further requires that the fibroblast cells are killed by a repeated irradiation.

Boyce et al. teach a method wherein fibroblast cells were grown in lethally irradiated 3T3 cells. Boyce et al. like the present claims call for the use of lethally irradiated 3T3 cells. Given that both Boyce et al. and the present invention grow epidermal cells on lethally irradiated 3T3 cells, the extracellular matrix recited in Applicant's claims would be inherent to the method of Boyce et al. See column 2, lines 43-47. When Applicant claims a property, which is inherently present in the prior art, the property does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Boyce et al. additionally teach that the 3T3 cells were removed from the culture, thus meeting the limitations of claims 2 and 3. See column 2, line 55. Boyce et al., however, fail to teach repeated irradiation of the 3T3 cells.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to repeat the step of killing fibroblast cells in the present method because Boyce et al. teach killing fibroblast cells to culture keratinocytes and it is well within the ordinary skill in the art to repeat any steps as necessary. One of ordinary skill in the art would be motivated to repeat said step in order to confirm that the fibroblast cells are killed such that a culture of consisting of epidermal cells is grown as taught by Boyce et al. The ordinary skilled artisan would reasonably expect that irradiation would kill the fibroblast cells during the second application because Boyce et al. teach that it kills cells.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite the word “killing” as a limitation to the present method. This language renders the claims vague and indefinite because it is unclear what Applicant intends killing to mean. Does Applicant intend “killing” to mean inhibition of cell growth, cessation of cell growth, or complete disruption or fragmentation of the cell?

The present claims are vague and indefinite because they claim a fibroblast “derived from” a mammal. “Derived” is a term that is non-specific and relative in nature for which Applicant provides no definition. This word provides no clarity as to what Applicant’s claimed

invention includes and what it does not include. Without a more specific definition of the claim, it is impossible to determine what and how many derivations comprise the invention.

Applicant's disclosure does not provide any definition as to the process of deriving these fibroblast. Moreover, the nature and number of the derivations to arrive at the invention

Applicant seeks to protect.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for epidermal target cells, does not reasonably provide enablement for hepatic target cells, as in claim 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,

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- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Given the factors above, Applicant has failed to teach how to make and use the invention commensurate with the scope of the claims. Although all factors have been considered the most relevant have been discussed below.

Applicant's invention is drawn to a method of culturing target cells by inoculating them with fibroblasts that have been cultured and killed. The breadth of the claims encompasses any target cell. Applicant's specification, however, only discloses epidermal target cells through the specification and in each of examples 1-4. Upon search of the prior art, there is no indication that fibroblast cells either living or dead can support the growth of cells other than epidermal cells such as keratinocytes. There are numerous examples in the prior art that fibroblast cells are relevant for the growth and proliferation of epidermal. For example Boyce et al., cited above, and Green et al., cited in prior office actions, exemplify that it is well known in the art that fibroblasts support the growth of epidermal cells such as keratinocytes. Therefore, given the nature of the invention, the breadth of the claims, the state of the prior art and the lack of sufficient disclosure and working examples in the specification, Applicant is enabled only for a method of proliferating epidermal target cells.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
October 21, 2002


TERRY MCKELVEY
PRIMARY EXAMINER